



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,385	11/21/2003	Margot O'Toole	22058-582) (BFLP 0169)	2575
30623	7590	11/04/2004	(A)	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			EXAMINER CHAUDHURI, ANIRUDDHO RAY	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/719,385

Applicant(s)

O'TOOLE ET AL.

Examiner

Aniruddho R Chaudhuri

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*; 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Sequence Compliance

1. The instant application is in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.
2. It appears that the only agents disclosed in the specification as filed are anti-BFLP0169 antibodies, see page 4, ¶ 1 (See groups VI and VIII). Therefore the claims have been restricted according to these antibodies. Alternatively, if applicant intends to claim additional agents disclosed in the specification as filed, then such agents would be subject to further restriction.

3. Applicant is required to amend claim 46 to replace "lupus lephritis" with "lupus nephritis".

Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 1-8, 34, drawn to an isolated nucleic acid molecule, vector, cell and method of making a polypeptide, classified in Class 530, subclass 300, Class 435, subclasses 320.1, 328 and 69.1.
 - II. Claims 9-14, 17-25, drawn to a purified polypeptide and pharmaceutical composition, classified in Class 530, subclass 350 and Class 514, subclass 2.
 - III. Claims 15, 16, 26-28, drawn to a fusion polypeptide and pharmaceutical composition, classified in Class 530, subclass 387.3 and Class 514, subclass 4.

For examination purposes, claim 16 reads on dependent on claim 15. Applicant is reminded that there is lack of antecedent basis for claim 16.

- IV. Claims 29-33, 52 and 53, drawn to an antibody and pharmaceutical compositions, classified in Class 530, subclass 387.1 and Class 424, subclass 130.1.
- V. Claims 35, 39-40, drawn to method of detection with a nucleic acid, classified in Class 435, subclass 6.
- VI. Claims 36-38, 41, and 42, drawn to method of detection with a compound that selectively binds to polypeptide (i.e. anti-BFLP0169 antibody), classified in Class 435, subclass 7.1.
- VII. Claims 43-48, drawn to a method for screening for therapeutic agents, classified in Class 435, subclass 4.
- VIII. Claims 49-51, drawn to a method of treating lupus nephritis with an agent that inhibits BFLP0169 activity (i.e. anti-BFLP0169 antibody), classified in Class 424, subclass 145.1.

Art Unit: 1644

5. Groups I, II, III and IV are different products. Nucleic acids, vector, host cells, polypeptides, fusion polypeptides, and antibodies differ with respect to their structures and physicochemical properties and modes of action, which require non-coextensive searches. Therefore, they are patentably distinct.

6. Groups V, VI, VII and VIII are different methods. These inventions are different with respect to ingredients, method steps, and endpoints, which require non-coextensive searches. Therefore, each method is patentably distinct.

7. (Groups I and V), (Groups II and VII) and (Groups IV and VI/VIII) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the nucleic acid of Group I can be used in producing a protein, in addition to of detecting and determining predisposition to disease recited.

In the instant case the polypeptide of Group II can be used as an immunogen to produce antibodies, in addition to the methods of detecting and determining predisposition to disease recited.

In the instant case the antibody of Group IV can be used for affinity purification, in addition to the methods of treating and detecting recited.

8. Groups I and (VI, VII, and VIII) are not related as product and processes of using.

Groups II and (V, VI and VIII) are not related as product and processes of using.

Group III and (V, VI, VII and VIII) are not related as product and processes of using.

Groups IV and (V, VI, VII) are not related as product and processes of using.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 1644

Species Election

10. *If Group III is elected:* Applicant is required to elect a specific member from the group:
- Fc region of an immunoglobulin molecule,
 - FLAG epitope, HIS tag, or
 - MYC tag.

These species are distinct because these molecules differ in structure and function; thus each species represents patentably distinct subject matter.

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

11. It is noted that the only autoimmune disease disclosed in the specification as filed appears to be lupus nephritis. Therefore, no species election on autoimmune diseases with respect to Groups V-VIII is set forth herein.

Applicant is invited to limit the claims to recite lupus nephritis.

Alternatively, if the specification does disclose autoimmune diseases other than lupus nephritis, then such autoimmune diseases would be subject to a species election, given that autoimmune diseases differ in etiologies and therapeutic endpoints.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Art Unit: 1644

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aniruddho Ray Chaudhuri whose telephone number is 571-272-0953. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Aniruddho Ray Chaudhuri (AC), Ph.D.

Patent Examiner

Technology Center 1600

October 29, 2004


PHILLIP GAMBEL, PH.D.
PRIMARY EXAMINER
TECH CENTER 1600
11/1/04